REMARKS:

This Amendment is intended to replace the Amendment After Final Rejection mailed July 29, 2011, and it is responsive to both the Final Office Action of April, 1, 2011 and the Advisory Action of August 17, 2011.

A Request for Continued Examiner is filed concurrently with this Amendment to assure entry and consideration of the amendment.

Status of the Claims

Claims 45 and 46 are amended to specify the bacterium as being a *Lactococcus* strain. Support for the amendment may be found, for example, in the summary of the invention, page 6, lines 23-29 and page 7, lines 9-13.

Claim 52 is new and further defines the pharmaceutical composition of claim 45 as an infusion mixture. Support for this feature may be found, for example, in the Detailed Description of the Invention on page 10, lines 5-17.

Claim 53 is new and further describes the *Lactococcus* strain of the pharmaceutical composition of claim 45 as a *Lactococcus lactis* strain.

Claim 54 is new and further describes the *Lactococcus* strain of the method of claim 46 as a *Lactococcus lactis* strain.

Claims 47 and 51 are cancelled without prejudice.

Claims 28-46, 48-50, and 52-54 remain in this application.

Claims 28-44 have been withdrawn.

Alleged Lack of Support for a *Lactococcus* Strain

In the Advisory Action, one of the reasons stated for not entering the Amendment of July 29, 2011 was:

> "While the specification does have support for Lactococcus lactis strain, there is not sufficient support for every species of the broad genus as claimed nor for every strain derived from the broad genus as claimed."

The Applicant respectfully disagrees. The inventors' contribution to the art is the finding that a *Lactococcus* bacterium could be utilized in a pharmaceutical composition adapted for application to localized infection of the skin. None of the prior art documents of record teach, motivate or suggest such a finding.

The Applicant submits that it is unreasonable to force the Applicant to limit this inventive contribution solely to the specific strain mentioned in the examples of the specification when it was clearly envisaged by the inventors that the lactic acid bacterium may be a *Lactococcus* strain and not simply limited to a specific *Lactococcus lactis* strain. In particular, para. [0020] of the U.S. Application as published substantiates the fact that the inventors saw the widespread applicability of the present invention across the whole *Lactococcus* genus.

Accordingly, it is submitted that it would be unreasonable to force the present inventors to limit their contribution to the art to one specific *Lactococcus* strain when the applicability of the invention is much broader.

Claim Rejections-35 USC §112

Claim 47 was rejected under 35 U.S.C. §112, fourth paragraph, for not further limiting claim 46.

This rejection is rendered moot, as claim 47 has been cancelled. Its subject matter was previously added to claim 46.

Claim Rejections-35 USC §102

Claims 45-47 and 49 were rejected under 35 U.S.C. §102(e) as being anticipated by WYNNE et al. US 7,125,708(WYNNE). This rejection is respectfully traversed for the reasons below.

Amended independent Claims 45 and 46 recite that the probiotic bacterium is a *Lactococcus* strain. New claims 53 and 54 further describe the *Lactococcus* strain as being *Lactococcus lactis*.

WYNNE discloses pharmaceutical compositions comprising *Lactobacillus pentosus* for the treatment of bacterial infections, such as urinary tract infections. The composition may be administered by physical contact with the skin, and as such could be considered to be adapted for application to localized infection of the skin.

WYNNE, however, relates solely to *Lactobacillus pentosus*.

Accordingly, the amended Claim set is novel over WYNNE, and withdrawal of the anticipation rejection is respectfully requested.

Moreover, WYNNE alone or in combination with any of the other cited prior art references does not teach, motivate or suggest that a *Lactococcus* strain (or *Lactococcus lactis* specifically) could be utilized to treat a localized skin infection as set out in the present application.

Claims 46 and 48 were rejected under 35 U.S.C. §102(e) as being anticipated by GLENN et al. US 20020159976(GLENN). This rejection is respectfully traversed for the reasons below.

Amended independent Claim 46, from which claim 48 depends, recite that the probiotic bacterium is a *Lactococcus* strain. New claims 53 and 54 further describe the *Lactococcus* strain as being *Lactococcus lactis*.

GLENN discloses pharmaceutical compositions comprising *Lactobacillus rhamnosus* or probiotic bacteria having expressible polynucleotide sequences derived from *Lactobacillus rhamnosus* and the compositions are disclosed for the prevention of wound infections. GLENN is silent as to how the composition may be administered and, in particular, if the compositions are administered locally. GLENN is also silent to a *Lactococcus*

strain, as GLENN relates solely to *Lactobacillus rhamnosus* and variants derived therefrom.

Accordingly, the amended Claim set is novel over GLENN, and withdrawal of the anticipation rejection is respectfully requested.

Moreover, GLENN alone or in combination with any of the other cited prior art references does not teach, motivate or suggest that a *Lactococcus* strain (or *Lactococcus lactis* specifically) could be utilized to treat a localized skin infection as set out in the present application.

Claims 45-47 were rejected under 35 U.S.C. §102(b) as being anticipated by MOLLET et al. US 5,756,665 (MOLLET). This rejection is respectfully traversed for the reasons below.

Amended independent Claims 45 and 46 recite that the probiotic bacterium is a *Lactococcus* strain. New claims 53 and 54 further describe the *Lactococcus* strain as being *Lactococcus lactis*.

MOLLET relates to compositions comprising:

i) a bacteriocin derived from *Micrococcus varians*; or

ii) a supernatant extract containing the bacteriocin in i) above,

primarily in cosmetic compositions. The cosmetic compositions are deemed to have activity against pathogenic infectious bacteria on the skin and may arguably be considered as pharmaceutical compositions.

MOLLET, however, relates solely to *Micrococcus varians*.

Accordingly, the amended Claim set is novel over MOLLET, and withdrawal of the anticipation rejection is respectfully requested.

Moreover, MOLLET alone or in combination with any of the other cited prior art references does not teach, motivate or suggest that a *Lactococcus* strain (or *Lactococcus lactis* specifically) could be utilized to treat a localized skin infection as set out in the present application.

Claim Rejections-35 USC §103

Claim 50 is rejected under 35 U.S.C. §103(a) as being unpatentable over MOLLET in view of TWOMEY et al. J. Diary Sci. 2000, 83(9), 1981-1988(TWOMEY). This rejection is respectfully traversed for the reasons below.

The position of the Official Action was that the Claims in relation to the treatment of mastitis are obvious in view of the above combination of prior art documents (one of which is the inventors' own prior art).

The argument presented in the Official Action was that MOLLET teaches a culture supernatant comprising a bacteriocin may find utility in a cosmetic composition. The Official Action continued to argue that TWOMEY relates to the treatment of mastitis using isolated lacticin 3147, and, thus, may find utility in the treatment of mastitis. The opinion present in the

Official Action was that a skilled person reading these documents together would arrive at the subject matter of Claim 50, *i.e.*, a treatment for mastitis using a supernatant.

Applicants disagree and respectfully argue that MOLLET discloses its compositions as being purely cosmetic in effect, with particular reference to creams and deodorants. The cosmetic compositions are qualified as having activity against pathogenic bacteria. A skilled person reading this would rationally understand that such compositions may show activity cosmetically against bacteria such as *acne vulgaris* or body odour causing bacteria.

However, in searching for a treatment to cure bovine infections, such as mastitis, the skilled person is extremely unlikely to consult a patent that reports human cosmetic compositions. There is no logical link between the two applications.

Indeed, it appears that the combination of MOLLET and TWOMEY is made with the aid of impermissible hindsight. The position appears to result from finding related features in documents with unrelated applications and an examination based on a hindsight perspective of the present invention. As noted in MPEP 2142, “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.”

Therefore, withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The fee of $52.00 for the extra dependent claim added is being paid online simultaneously herewith by credit card.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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